UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,925	02/06/2004	Brien E. Pierpont	P06547US1	8476
ZARLEY LAW FIRM P.L.C. CAPITAL SQUARE 400 LOCUST, SUITE 200 DES MOINES, IA 50309-2350			EXAMINER	
			BOUCHELLE, LAURA A	
			ART UNIT	PAPER NUMBER
			3763	
			MAIL DATE	DELIVERY MODE
			08/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

#### UNITED STATES PATENT AND TRADEMARK OFFICE

\_\_\_\_\_

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

\_\_\_\_\_

Ex parte BRIEN E. PIERPONT and JAMES A. COYLE

Appeal 2009-011920 Application 10/773,925 Technology Center 3700

Before LINDA E. HORNER, MICHAEL W. O'NEILL, and KEN B. BARRETT, *Administrative Patent Judges*.

O'NEILL, Administrative Patent Judge.

DECISION ON APPEAL<sup>1</sup>

mode) shown in the PTOL-90A cover letter attached to this decision.

<sup>&</sup>lt;sup>1</sup> The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery

#### STATEMENT OF THE CASE

Brien E. Pierpont and James A. Coyle (Appellants) seek our review under 35 U.S.C. § 134 of the final rejection of claims 1-13. We have jurisdiction under 35 U.S.C. § 6(b).

#### The Invention

The claimed invention is to a catheter assembly used in performing medical procedures such as cardiac catheterization and angioplasty.

Claim 1, reproduced below, is illustrative of the subject matter on appeal.

1. A catheter assembly, comprising,

an elongated hollow anchoring catheter having a distal end, a proximal end and a tubular wall with inner and outer surfaces,

a hollow guiding catheter having a distal end and a proximal end housing said anchoring catheter,

a first anchoring balloon member attached to the outer surface of said tubular wall of the anchoring catheter and adapted upon inflation to project outwardly from said tubular wall to engage the guiding catheter and secure said anchoring catheter within said guiding catheter,

an elongated treatment catheter extending through an opening in said tubular wall of said anchoring catheter and having a distal end, and

a guide wire extending through the treatment catheter and along which the treatment catheter is slidable.

# The Rejection

The following Examiner's rejection is before us for review:

Claims 1-13 are rejected under 35 U.S.C. § 103(a) as obvious over Pierpont (U.S. Patent No. 5,484,412, issued Jan. 16, 1996) in view of Crittenden (U.S. Patent No. 4,988,356, issued Jan. 29, 1991).

## SUMMARY OF DECISION

We AFFIRM.

## **OPINION**

#### Issue

In light of the Appellants' contentions and the Examiner's positions, the dispositive issue before us is as follows:

Whether one of ordinary skill in the art would have used the teachings of Crittenden to improve Pierpont to have an opening in the tubular wall of the anchoring catheter through which a treatment catheter extends.

## Analysis

## Prima Facie Case of Obviousness

The Examiner found that Pierpont discloses a catheter assembly for performing an angioplasty procedure that comprises substantially all of the claimed features. Ans. 3. The Examiner acknowledges "Pierpont fails to disclose that the treatment catheter extends through an opening in the tubular wall of the anchoring catheter." *Id.* The Examiner found that Crittenden teaches a similar catheter assembly for performing an angioplasty procedure that utilizes a side slit opening in the catheter for introducing an elongated element, *viz.*, a guidewire. *Id.* The Examiner concludes that a prima facie case of obviousness has been established by the combination of Pierpont and Crittenden because one of ordinary skill in the art would have modified Pierpont's anchoring catheter to have an opening in the tubular wall thereof, through which Pierpont's treatment catheter would extend by the teachings of Crittenden, in order to enable medical technicians to introduce and remove additional devices into and out of indwelling catheters, resulting in

improved ease of use and safety to the patient. Ans. 3-4. Appellants appear not to contest the Examiner's findings concerning the content of Pierpont and Crittenden. *See* App. Br. and Reply Br., *passim*. As such, we adopt the Examiner's findings as our own.

Instead, Appellants contend that the Examiner's combination of Pierpont and Crittenden does not establish a prima facie case of obviousness because Crittenden does not teach "a treatment catheter extending through an opening in the tubular wall of the anchoring catheter" in order to cure the deficiency of Pierpont. App. Br. 3-4. Rather, Appellants contend that Crittenden teaches "a guide wire 14 that extends through a slit 28 of a catheter 10." App. Br. 4.

The Court stated in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) that, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." The Court elaborated that when considering obviousness of a combination of known elements, the operative question is "whether the improvement is more than the predictable use of prior-art elements according to their established functions." *Id.* 

We are not persuaded by Appellants' arguments that the Examiner failed to establish a prima facie case of obviousness. In considering the obviousness of Pierpont in view of Crittenden, we note that the combination is one of known elements. Further, it does not appear that Appellants' improvement is more than the predictable use of prior-art elements according to their established functions. In the instant case, the Examiner has found that the prior art contained a "base" device (i.e., Pierpont's

catheter assembly) upon which the claimed invention can be seen as an "improvement." The Examiner also found that the prior art contained a "comparable" device (i.e., Crittenden's catheter assembly) that is not the same as the "base" device, but that has been improved in the same way as the claimed invention. The Examiner found that one of ordinary skill in the art could have applied the known "improvement" technique of Crittenden in the same way to the "base" device of Pierpont and the results would have been predictable to one of ordinary skill in the art. Moreover, we note that Appellants have not suggested that the combination of Pierpont and Crittenden would yield an unpredictable result.

The Appellants' contention, that "Crittenden does not teach a treatment catheter 10 extending through an opening in another catheter and instead teaches a guide wire extending through an opening in a treatment catheter" (App. Br. 4), is unpersuasive because it appears to be predicated on a belief that a reference must describe a limitation *in haec verba*. There is no such requirement. *See In re Bode*, 550 F.2d 656, 660 (CCPA 1977). Accordingly, it is permissible for the Examiner to rely on Crittenden for the teaching of inserting an elongate member through the sidewall of a catheter (Ans. 3, 5) in order to develop the Examiner's prima facie case for obviousness, and Appellants have not persuaded us that one of ordinary skill in the art would fail to recognize the applicability of this teaching to elongate members other than guide wires (i.e., a catheter).

We are not persuaded by Appellants' argument (*see* Reply Br. 2) that the Examiner is relying on generalities or is oversimplifying Appellants' claims. We are further not persuaded by Appellants' argument that "[Appellants assert] that the general teachings from the Pierpont and

Crittenden reference[s] cannot form the basis of a prima facie case of obviousness" (Reply Br. 3) because Appellants have not provided any evidence supporting why the general teachings of the references may not be relied upon in an obviousness rejection. Regardless, we find that the Examiner has relied on more than a general teaching because the Examiner modified Pierpont's anchoring catheter to have a slit which Pierpont's treatment catheter extends through according to the teachings of Crittenden and it would be within the level of skill of one of ordinary skill in the art to know how to practically combine the teachings of Pierpont and Crittenden. *No Reason to Combine* 

Appellants contend that one of ordinary skill in the art would have "no reason to combine the Pierpont and Crittenden references." App. Br. 4;

Reply Br. 3. Appellants also contend that Pierpont and Crittenden are directed towards different objectives and solve different problems. App. Br.

5. More particularly, Appellants allege that Pierpont "is directed toward improving the advancement of the balloon dilatation catheter," whereas Crittenden "is directed towards avoiding a long exchange guide wire, exchanging guide wires within a catheter, minimizing tension load on a guide wire and minimizing the risk of guide wire entanglement in procedures when multiple guide wires are used." App. Br. 5. Thus, Appellants contend that "one skilled in the art would not have a reason to consider the Crittenden reference as Pierpont was not interested in solving problems associated with a guide wire." App. Br. 5.

While the requirement for a teaching, suggestion, or motivation (the TSM test) to combine known elements in order to show that the combination would have been obvious may be "a helpful insight," it cannot be used as a

rigid and mandatory formula. *KSR*, 550 U.S. at 418-19. Rather, rejections on obviousness grounds need to be supported by "some articulated reasoning with some rational underpinning" to combine the known elements in the manner required in the claim at issue. *Id.* at 418 (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Accordingly, "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* at 417.

We note that Appellants have not demonstrated that the Examiner's reason for combining the references lacks rational underpinning because rational underpinning does not require demonstration by explicit teachings, suggestions, or motivations. *See KSR*, 550 U.S. at 418-19. The Examiner proposed to incorporate the features of the slitted catheter disclosed in Crittenden into the catheter assembly of Pierpont, which serves to improve the Pierpont invention. Ans. 3-4. By giving Pierpont's catheter assembly a slit as taught by Crittenden, the catheter assembly is improved in a straightforward and predictable way. *See KSR*, 550 U.S. at 417. Modifying Pierpont's anchoring catheter to be a slitted catheter like Crittenden's slitted catheter would provide the simple improvement necessary to achieve this result and would require no more insight than the common sense to use an existing device to improve a similar device in the manner the Crittenden device was intended to operate. *See KSR*, 550 U.S. at 417. The Examiner's

modification appears to use Pierpont, as a piece of prior ready for improvement, and modifies Pierpont by Crittenden's teachings in order to yield an improved catheter assembly.

Appellants contend that "Pierpont's solution added extra structural support to the balloon dilatation treatment catheter" while "Crittenden inherently weakens the balloon dilatation catheter structure 10 while [sic] by placing a slit 28 therein" (App. Br. 6) so that one of ordinary skill in the art would not combine the references to arrive at the claimed invention. After reviewing Appellants' proffered passages from Pierpont (i.e., column 1, line 51 through column 2, line 11 and column 3, lines 33-40), we are not convinced by Appellants' contention that Pierpont added extra structural support to the balloon dilatation catheter. The cited passages of Pierpont discuss the structural support provided by the guiding catheter, not any added support to the balloon dilatation or treatment catheter. Additionally, even if the slit in the catheter of Crittenden weakens the catheter, we are not convinced that this is would be undesirable because Appellants' Figure 4 embodiment has a slit for its opening and Appellants have not alleged that the slitted catheter is unfit for its intended purpose as being of a weakened construction.

## Hindsight

We are not convinced by Appellants' arguments that the combination of Pierpont and Crittenden is the product of impermissible hindsight. *See* Reply Br. 3. Indeed, the Examiner made findings regarding Crittenden's teachings, and points to those teachings as providing a motivation to modify Pierpont. *See* Ans. 3-4, 5. Therefore, we determine that the Examiner did not rely on impermissible hindsight, as Appellants urge, but rather relied on

Appeal 2009-011920 Application 10/773,925

the knowledge of those skilled in the art at the time of the invention and took into account the inferences and creative steps that would have been employed by a person of ordinary skill in the art.

## Appellants' Additional Contentions toward Nonobviousness

Appellants note that one of the inventors, namely, Dr. Pierpont, is one of advanced skill in the art and that the Crittenden reference was well known to Dr. Pierpont, yet for many years Dr. Pierpont did not contemplate using Crittenden's teachings. App. Br. 6. Appellants contend that

[w]hen considering that Dr. Pierpont is one of advanced skill in the art and had fully considered the teachings of the prior art references cited without combining them for several years[, Appellants assert] this is extremely strong evidence that the combination of these two references is not obvious to one of ordinary skill in the art.

# App. Br. 7.

The Examiner's position is that

[t]he bottom line is that these two teachings were available to the inventor at the time of [the] invention, and the fact that it did not occur to the inventor to make the combination until a later time does not support the assertion that the combination would not have been obvious.

#### Ans. 6.

We agree with the Examiner. Even if the inventors themselves were surprised to discover that the Crittenden improvement was applicable to the Pierpont catheter assembly, this does not establish that one of ordinary skill in the art would have been surprised by the result because the obviousness standard is an objective standard rather than a subjective one.

Application 10/773,925

## **CONCLUSION**

In view of the foregoing, it would have been obvious to one of ordinary skill in the art to have used the teachings of Crittenden to improve Pierpont to have an opening in the tubular wall of the anchoring catheter through which a treatment catheter extends.

## **DECISION**

The Examiner's rejection of claims 1-13 under 35 U.S.C. § 103(a) as being obvious over Pierpont in view of Crittenden is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv) (2007).

# <u>AFFIRMED</u>

mls

ZARLEY LAW FIRM P.L.C. CAPITAL SQUARE 400 LOCUST, SUITE 200 DES MOINES, IA 50309-2350